(11) Application No. AU 2010200932 A1

(19) AUSTRALIAN PATENT OFFICE

(54) Title
Seal device with adjustable aperture

(51)[6] International Patent Classification(s)
A61M 39/06 (2006.01)
A61M 39/06 20060101AFI2010031 5BHAU

(21) Application No: 2010200932

(22) Application Date: 2010.03.11

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/164,094	2009.03.27	US
12/714,823	2010.03.01	US

(43) Publication Date : 2010.10.14

(43) Publication Journal Date : 2010.10.14

(71) Applicant(s)
Tyco Healthcare Group LP

(72) Inventor(s)
Battles, Christopher A.

(74) Agent/Attorney
Spruson & Ferguson, Level 35 St Martins Tower 31 Market Street, Sydney, NSW, 2000

2010200932 11 Mar 2010

SEAL DEVICE WITH ADJUSTABLE APERTURE

ABSTRACT

A seal device (100) comprising: a seal housing defining a central axis, the seal housing having an inner wall (20) and an outer wall (30), the inner wall (20) defining an opening along the central axis; a rotatable head (10) mounted to the seal housing; at least one finger (11) pivotally mounted to the rotatable head (10), the fingers (11) defining an aperture (15) for reception of a surgical instrument; and a cam (16) mounted to the rotatable head (10) for pivoting the fingers (11) upon rotation of the rotatable head (10), the at least one finger (11) configured to reduce the amount by which the surgical instrument may be moved off-axis relative to the central axis.

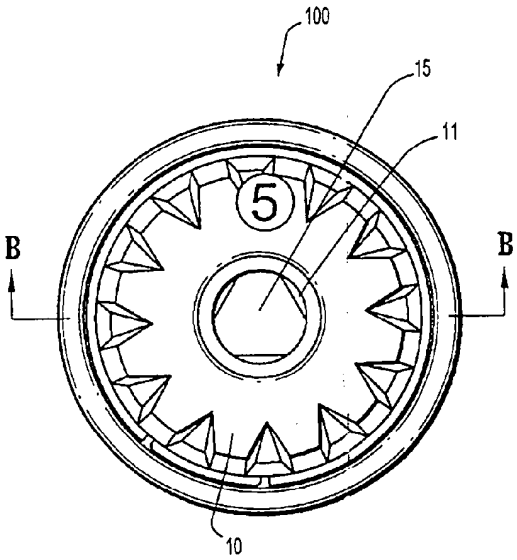

FIG. 1

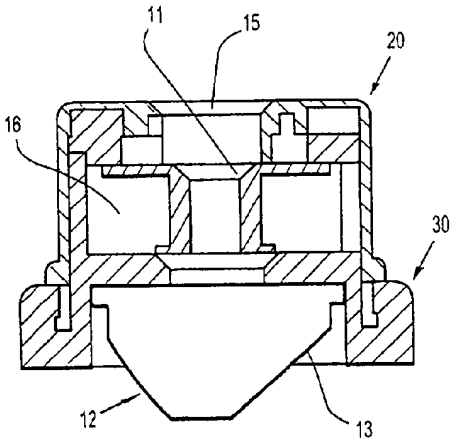

FIG. 2

2010200932 11 Mar 2010

S&F Ref: 942995

AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

Name and Address of Applicant :	Tyco Healthcare Group LP, of 60 Middletown Avenue, North Haven, Connecticut, 06473, United States of America
Actual Inventor(s):	Christopher A. Battles
Address for Service:	Spruson & Ferguson St Martins Tower Level 35 31 Market Street Sydney NSW 2000 (CCN 3710000177)
Invention Title:	Seal device with adjustable aperture

The following statement is a full description of this invention, including the best method of performing it known to me/us:

5845c(2584174_1)

SEAL DEVICE WITH ADJUSTABLE APERTURE

CROSS REFERENCE TO RELATED APPLICATION

The present application claims the benefit of and priority to U.S. Provisional Application Serial No. 61/164,094 filed on March 27, 2009, the entire contents of which are incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates to an adjustable aperture seal system adapted to permit the introduction of surgical instrumentation into a patient's body.

2. Background of Related Art

Minimally invasive surgical procedures, such as laparoscopic surgery, result in reduced trauma for a patient than an equivalent open procedure. In this procedure, trocar assemblies including narrow hollow tubes called cannula are inserted into small incisions made into a patient's skin by a trocar. Elongated surgical instruments are inserted into the patient's body cavity through the cannula.

Often the patient's body cavity has been insufflated with carbon dioxide to separate the cavity wall from the internal organs therein. This creates a working and a viewing space. Therefore, a tight seal must be maintained between the body cavity and the outside environment.

Maintaining such a seal is complicated since it is often desirable to insert and remove several surgical instruments through one cannula in a single surgical procedure. While it is ideal to use the smallest available surgical instruments, some complex instruments may not be able to fit inside such a small cannula. The seal that is used must be sized to receive the instrument.

Ideally, a surgeon should be able to use one seal system to accommodate all the instruments used during the surgical procedure. The known seals are deficient in numerous ways, including an inability to accommodate instrumentation or various sizes and inability to preserve the integrity of the seal as instrumentation is manipulated.

2010200932 11 Mar 2010

OBJECT OF THE INVENTION

It is the object of the present invention to substantially overcome or ameliorate one or more of the disadvantages of the prior art.

SUMMARY

The present disclosure describes a seal device adapted to permit the introduction and use of surgical instruments of various dimensions into a patient's body while maintaining a seal around the instruments. In one embodiment, a seal device is described in which the diameter of an aperture, through which surgical instruments are inserted, is adjustable by rotating a head coupled to a cam that pivots fingers defining the aperture, This allows the seal device to accommodate a range of instruments having a variety of tip configurations and a variety of diameters.

In a particular embodiment of the present invention, a seal device comprises a seal housing defining a central axis, the seal housing having an inner wall and an outer wall, the inner wall defining an opening along the central axis; a rotatable head mounted to the seal housing; at least one finger pivotally mounted to the rotatable head, the fingers defining an aperture for reception of a surgical instrument; and a cam mounted to the rotatable head for pivoting the fingers upon rotation of the rotatable head, the at least one finger configured to reduce the amount by which the surgical instrument may be moved off-axis relative to the central axis. The seal device may also include an instrument seal for substantially sealing about the surgical instrument, and a zero-closure seal for providing a substantial seal in the absence of a surgical instrument. The rotatable head may include indicia which provide an indication to a user of the appropriate size of an instrument that may be inserted therethrough. The indicia may include a window defined by the rotatable head through which numerical markings may be visible.

BRIEF DESCRIPTION OF THE DRAWINGS

By way of description only, embodiments of the disclosure will be described with reference to the accompanying drawings, in which:

Fig. 1 is a top view of a seal device according to an embodiment of the present disclosure;

Fig. 2 is a side cross sectional view of the seal device of Fig. 1;

Fig. 3a is a perspective view of the seal device adjusted to form a first aperture;

Fig. 3b is a top view of a the seal device of Fig. 3a;

Fig. 4a is a perspective view of the seal device adjusted to form a second aperture; and

Fig. 4b is a top view of the seal device of Fig. 4a.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Particular embodiments of the present disclosure will be described herein with reference to the accompanying drawings. As shown in the drawings and as described throughout the following descriptions, and is traditional when referring to relative positioning on an object, the term "proximal" refers to the end of the apparatus that is closer to the user and the term "distal" refers to the end of the apparatus that is further from the user. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

A seal device 100 allows for the introduction and manipulation of a variety of instruments adapted for insertion through a trocar or cannula assembly while preserving the atmospheric integrity of the body cavity from gas or fluid leakage. Examples of instrumentation used in such procedures includes, but is not limited to, clip appliers, graspers, dissectors, retractors, staplers, laser probes, photogenic devices, endoscopes and laparoscopes, tubes and the like. Such instruments will be collectively referred to herein as "instruments or instrumentation".

The seal device 100 is adapted for use with a trocar assembly, including an obturator and a cannula, and is utilized for minimally invasive, such as endoscopic or laparoscopic procedures. The seal device 100 cooperates with the obturator or other instruments extending through the cannula to form a seal around the outer surface of the instrument and preclude the passage of fluids or gases through the body cavity and trocar assembly.

In one embodiment, the seal device 100 includes an aperture 15 of variable diameter defined by the cam fingers 11. Aperture 15 allows for the passage of surgical instruments inserted therethrough. The seal device 100 can be described as having an inner housing 20 and an outer housing 30. The inner housing 20 has spaces formed therein to accommodate rotational movement of the cam 16 and the cam fingers 11. When a surgeon desires to adjust the diameter of aperture 15, rotatable head 10 is rotated. When rotated, the rotatable head 10 rotates a cam 16 which in turn pivots cam fingers 11. The cam fingers II collectively define aperture 15. By pivoting cam fingers 11, the surgeon may adjust the size of the aperture 15. Figs. 3a-3b and Figs. 4a-4b show the seal device 100 after the rotatable head has been positioned to define an aperture 15 of different

2010200932 11 Mar 2010

diameters, e.g., 5mm and 10mm, respectively. The seal device 100 can also define numerous apertures between 5mm and 20mm, e.g., 7mm, or any other size aperture.

The rotatable head 10 may include indicia which provides an indication to a user of the appropriate size of an instrument that may be inserted therethrough. For example, the rotatable head 10 shown in Figures I through 4(b) defines a window through which numerical markings may be visible. In this manner, a user may be provided with an indication that the cam fingers are suitably positioned for insertion of e.g., a 5mm instrument, a 10mm instrument, etc.

Adjustment of the cam fingers 11 in this manner may help prevent seal leakage, since the cam fingers may help reduce the amount by which an instrument inserted and used therein may be moved off-axis. By reducing the amount by which an instrument may be moved off-axis, there may be a reduced likelihood that a gap will be formed between the instrument and the instrument seal 13.

In one embodiment, the seal device 100 has a proximal end and a distal end. The proximal end of the seal device 100 is adapted to receive an instrument. The distal end of the seal device is adapted to engage the trocar assembly. Beneath the distal end of the seal device are a zero-closure valve, e.g., duckbill seal 12 and an instrument seal 13. The instrument seal 13 is adapted to form a tight seal with the trocar assembly.

The duckbill seal 12 prevents fluid and/or gas leakage after an instrument is withdrawn from the seal device 100. In one embodiment, the duckbill seal 12 is a one-way elastomeric member that allows for the insertion of instrumentation while inhibiting fluid and gas leakage between the shaft of the instrument and the duckbill seal 12.

Cam fingers 11, duckbill seal 12, and instrument seal 13 may be made from a flexible and/or elastic material, such as a urethane, silicone, natural or synthetic rubber or other elastomeric material. The material may be resistant to tears and should be impervious to gases and fluids. The selected material can be coated or impregnated with a therapeutic agent or material, such as an oligodynamic metal or an antimicrobial medium.

A fabric material, e.g., SPANDEX containing a mixture of LYCRA and NYLON may be superposed over cam fingers II, duckbill seal 12, and instrument seal 13 to minimize the potential of piercing, penetrating, or tearing by the instrumentation.

In another embodiment (not shown), a septum valve having a preformed puncture or crossed slits or a similar valve that is biased inward to provide a fluid/gas seal both when an instrument is inserted therethrough and in the absence of an instrument, can be used instead of or in conjunction with duckbill seal 12.

2010200932 11 Mar 2010

It will be understood by those skilled in the art that various modifications and changes in form and detail may be made therein without departing from the scope and spirit of the present disclosure. Accordingly, modifications and changes in form and detail may be made therein without departing from the scope and spirit of the present disclosure.

2010200932 11 Mar 2010

The claims defining the invention are as follows:

1. A seal device, comprising:

a seal housing defining a central axis, the seal housing having an inner wall and an outer wall, the inner wall defining an opening along the central axis;

a rotatable head mounted to the seal housing;

at least one finger pivotally mounted to the rotatable head, the fingers defining an aperture for reception of a surgical instrument; and

a cam mounted to the rotatable head for pivoting the fingers upon rotation of the rotatable head, the at least one finger configured to reduce the amount by which the surgical instrument may be moved off-axis relative to the central axis.

2. The seal device of claim 1, further comprising an instrument seal for substantially sealing about the surgical instrument.

3. The seal device of claim 1, further comprising a zero-closure seal for providing a substantial seal in the absence of a surgical instrument.

4. The seal device of claim 1, wherein the at least one finger includes three fingers.

5. The seal device of claim 1, wherein rotatable head includes indicia which provide an indication to a user of the appropriate size of an instrument that may be inserted therethrough.

6. The seal device of claim 1, wherein the indicia includes a window defined by the rotatable head through which numerical markings may be visible.

7. A seal device substantially as hereinbefore described with reference to the accompanying drawings.

Dated 10 March, 2010
Tyco Healthcare Group LP
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

(2578043_2):PRW

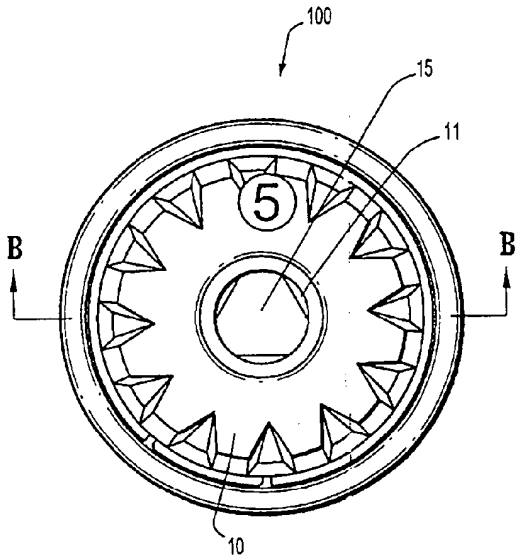

FIG. 1

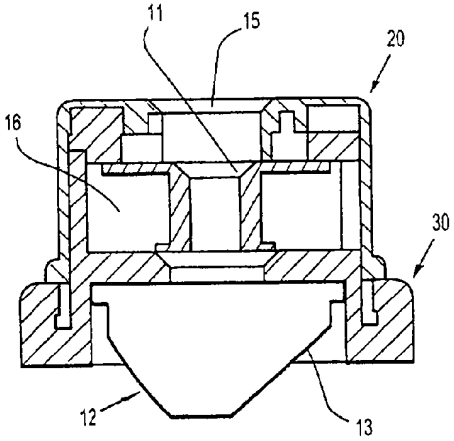

FIG. 2

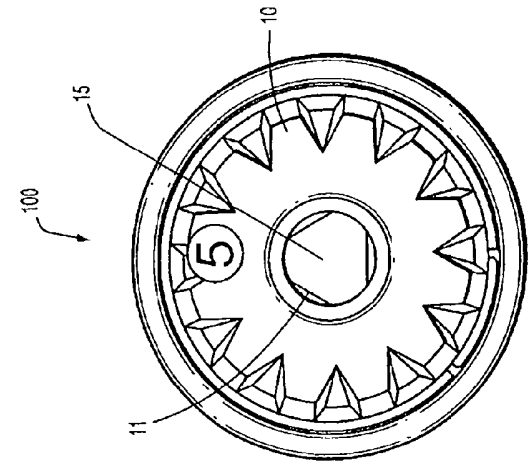

FIG. 3b

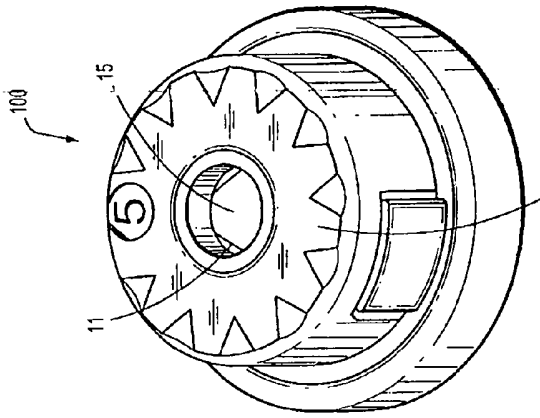

FIG. 3a

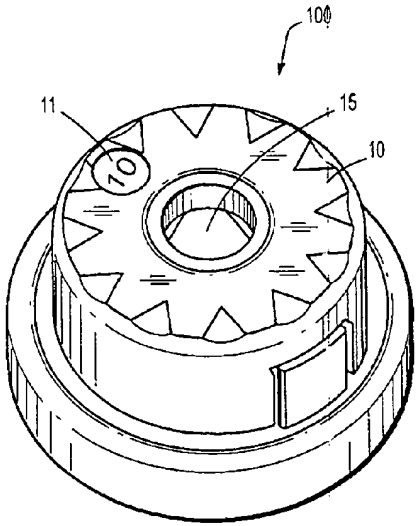

FIG. 4a

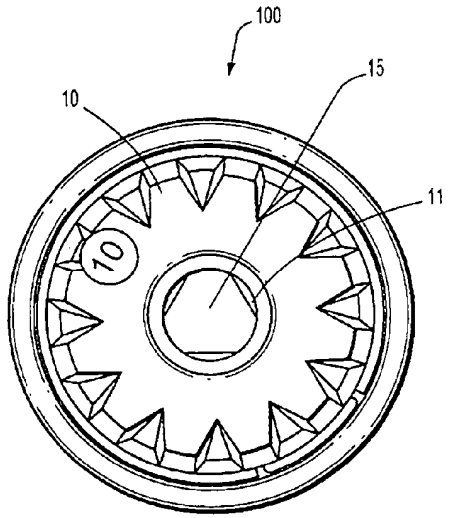

FIG. 4b